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10/586,877	07/21/2006	Takeshi Ikemoto	016912-0216	8114

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EXAMINER	
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ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,877	IKEMOTO ET AL.	
	Examiner	Art Unit	
	SCARLETT GOON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-9* is/are pending in the application.

4a) Of the above claim(s) *5-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2 and 5-9* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4 September 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicants' Amendment and Remarks filed on 29 December 2008 in which claims 3 and 4 were cancelled, claims 1 and 2 are amended to change the scope and breadth of the claims, and new claims 5-9 are added.

Claims 1, 2 and 5-9 are pending in the instant application.

Priority

This application is a National Stage entry of PCT/JP2005/000735 filed on 21 January 2005 and claims priority to Japan foreign application 2004-012764 filed on 21 January 2004. A certified copy of the foreign priority document in Japanese has been received. No English translation has been received.

Information Disclosure Statement

The information disclosure statement filed 4 September 2008 fails to comply with 37 CFR 1.97(c) because it lacks a statement as specified in 37 CFR 1.97(e). It has been placed in the application file, but the information referred to therein has not been considered. The IDS dated 4 September 2008 was filed after the mailing date of the first Office Action, mailed on 27 August 2008.

Rejections Withdrawn

In view of the cancellation of claims 3 and 4, all rejections made with respect to claims 3 and 4 in the previous Office Action are withdrawn.

These rejections have been **withdrawn**.

Election/Restrictions

Newly submitted claims 5-9 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: New claims 5-9 are directed to a method for reducing wrinkles occurring in photo-aging skin, whereas original claims 1 and 2 entirely are directed to an antiwrinkle agent comprising an eugenyl glycoside. Inventions of claims 1 and 2 and the invention of claims 5-9 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product, eugenyl glucoside, can be used in a materially different process, such as in the method for the treatment of androgenetic alopecia.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 5-9 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Moreover, since applicant has received an action on the merits for all pending claims 1-2, according to MPEP § 819, the general policy of the Office is not to permit the applicant to shift to claiming another invention such as new claims 5-9.

Claims 1 and 2 are examined on its merits herein.

The following are new ground(s) or modified rejections necessitated by Applicants' amendment, filed on 29 December 2008, wherein the limitations in pending claims 1 as amended now have been changed; claim 2 depends from claim 1. The limitations in the amended claims have been changed and the breadth and scope of those claims have been changed. Therefore, rejections from the previous Office Action, dated 27 August 2008, have been modified and are listed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over PG Pub No. US 2003/0054021 A1 by Dalko *et al.* (of record), in view of journal publication by Hamada *et al.* (PTO-892, Ref. U), further in view of journal publication by Wang *et al.* (PTO-892, Ref. V).

Dalko *et al.* teach a composition comprising 7-oxo-DHEA derivatives and a method for treating the adverse signs of aging of the skin by administration of the said composition (paragraphs 0003 and 0082). "Signs of the aging skin" include wrinkles and fine lines, loss of firmness and/or elasticity of the skin, cutaneous atrophy, a more irregular skin grain with presence of dilated pores, loss of radiance of the skin and/or pigmentary marks (paragraph 0083). The composition can further comprise 5α-reductase inhibitors that can be selected from retinoids, sulfur and sulfur derivatives, zinc salts, selenium chloride, vitamin B6, a mixture of capryloyl glycine, sarcosine and an extract of *Cinnamomum zeylanicum*, an extract of *Laminaria saccharina*, an extract of *Spiraea ulmaria*, plant extracts from various species including *Salvia oficinalis*, an extract of *Serenoa repens*, plant extracts of the genus Silybum, plant extracts containing sapogenins, and extracts of *Eugenia caryophyllata* containing eugenol or eugenyl glucoside (paragraph 0115-0129). Compounds containing a 5α-reductase inhibitor are particularly suitable for treating seborrhoea and/or hirsutism and/or androgen-dependent alopecia (paragraph 0130). The 5α-reductase inhibitor can constitute from 0.01% to 5% of the total weight of the composition (paragraph 0130).

Although Dalko *et al.* teach that *Eugenia caryophyllata* contains eugenol or eugenyl glucoside, Dalko *et al.* do not explicitly indicate whether eugenol or eugenyl glucoside is more preferable over the other.

Hamada *et al.* teach the treatment of androgenetic alopecia using eugenyl glucoside as a precursor for eugenol. Eugenol has a specific odor and is volatile, whereas a glycoside of eugenol is an odorless, hydrophilic white powder that is stable

(applicant supplied translation). Eugenol generated from eugenyl glucoside showed a much stronger 5α-reductase inhibitory effect than other related compounds and plant extracts (Table 1). In a clinical pilot study, the efficacy rate of a hair growth agent containing 0.5% eugenyl glucoside was 83.3% (abstract).

Wang *et al.* teach the isolation and structural elucidation of four glycosidically bound flavor precursors from nonvolatile fractions of sage extracts, *Salvia officinalis*. The major component of the nonvolatile fractions is eugenylglucoside, compound (4), isolated in 260 mg (p. 2509, column 2, subheading "Extraction and Isolation Procedures").

It is noted that Dalko *et al.* and Hamada *et al.* teach 5α-reductase inhibitors as useful for treating seborrhoea and/or hirsutism and/or androgen-dependent alopecia, not as an antiwrinkle agent. However, as the 5α-reductase inhibitor, specifically eugenyl glucoside, is not used alone, but rather, in a composition useful for treating the adverse signs of aging of the skin, including wrinkles (paragraph 0082 in Dalko *et al.*), the composition that includes eugenyl glucoside would necessarily also treat wrinkles. Thus, the presence of eugenyl glycoside in a composition for treating the adverse signs of aging of the skin would inherently also function as an antiwrinkle agent.

Moreover, the recitation of "antiwrinkle agent" is considered to be an "intended use" of the composition, and is therefore not given any patentable weight. Applicant is requested to note that the "intended use" of a composition will not further limit the claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly

claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Dalko *et al.*, concerning composition comprising 7-oxo-DHEA derivatives and 5α-reductase inhibitors, and a method for treating the adverse signs of aging of the skin by administration of the said composition, with the teachings of Hamada *et al.*, regarding the use of eugenyl glucoside as a precursor for the generation of eugenol, with the teachings of Wang *et al.*, regarding nonvolatile extracts of *Salvia officinalis* containing eugenylglucoside. Since Dalko *et al.* teach that extracts of *Eugenia caryophyllata* that contain eugenol or eugenyl glucoside can be used as the 5α-reductase inhibitors in their composition, and Hamada *et al.* teach that because eugenol has a specific odor and is volatile, eugenyl glucoside, which is odorless and non-volatile, can be used as a precursor for the generation of eugenol, one would have been motivated to combine the teachings and use eugenyl glucoside in a composition, which would have the same resultant properties as eugenol, but lacking the specific odor of eugenol. Moreover, one would have been motivated to combine the teachings and use eugenyl glucoside as the 5α-reductase inhibitor in the composition disclosed by Dalko *et al.* because Hamada *et al.* teach that eugenol generated from eugenyl glucoside showed a much stronger 5α-reductase inhibitory effect than other related compounds and plant extracts. Furthermore, since Dalko *et al.* indicate that eugenol and eugenyl glucoside is the active ingredients of interest from *Eugenia caryophyllate*, and Wang *et al.* teach that significant amounts of eugenyl glucoside can

be extracted from *Salvia officinalis*, one would not be limited to eugenyl glucoside from extracts of *Eugenia caryphyllata*.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 29 December 2008 with respect to the rejection of claims 1-4 made under 35 USC § 103(a) as being unpatentable over PG Pub No. US 2003/0054021 A1 to Dalko *et al.*, have been fully considered but are moot in view of the modified ground of rejections above.

Specifically, Applicants argue that although the Dalko *et al.* reference discloses extracts of *Eugenia caryophyllata* containing eugenol or eugenyl glucoside, extracts of *Eugenia caryophyllata* or of the clove bud contain substantially no eugenyl glucoside, as evidenced by Hamada *et al.* (Exhibit 1) and "Botanicals: A Phytocosmetic Desk Reference" published by CRC Press (Exhibit 2). Furthermore, Applicants argue that since Hamada *et al.* show that the inhibitory activity of eugenyl glycoside is only about 1% of that of eugenol, one of ordinary skill in the art would not have been motivated to prepare an antiwrinkle composition comprising a eugenyl glucoside-containing extract of *Eugenia caryophyllata* in an amount of 1 to 4% by weight. These arguments are not persuasive because, as indicated in the modified rejection above, one would have been motivated to combine the teachings and use eugenyl glucoside in place of eugenol in the composition disclosed by Dalko *et al.* because Hamada *et al.* teach that eugenyl

glucoside can be used as a precursor for eugenol in a composition since eugenol is volatile and has a specific odor, properties that are not found in eugenyl glucoside. The new grounds of rejection for the currently amended claims, necessitated by Applicant's amendments, are as indicated above.

Conclusion

In view of the rejections to the pending claims set forth above, no claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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